UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/506,078	02/16/00	CAMPOS M	PC10202A

EXAMINER	
FOLEY,S	
ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 10/03/01

023913
PFIZER INC
150 EAST 42ND STREET
5TH FLOOR - STOP 49
NEW YORK NY 10017-5612

HM12/1003

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/506,078	Applicant(s) CAMPOS ET AL.	
	Examiner Shanon A. Foley	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 June 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *7* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Drawings

Applicant has satisfactorily amended the specification to include a complete brief description for each drawing originally submitted. Drawing corrections and/or the substitute sheets of drawings that were indicated in the Notice of Draftspersons Patent Drawing Review is held in abeyance until the case is deemed allowable.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 11, 13, and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons of record.

Applicant points to excerpts in the specification that support the claim language and reiterates that the claims intend to encompass all endogenously synthesized peptides, which is not limited to hormones and enzymes.

A review of the claims in view of the passages cited by applicant has been made. It is easily discerned where the claim language is derived from in the specification. That is not the issue. The claims are directed eliciting an immune response to any peptide made endogenously in the invertebrate, including vital proteins required for all normal functioning of the organism and those proteins whose functions are unknown and/or undiscovered. This meaning is explicitly implied in the claims, and is clearly not reflecting what applicant intends based on reading the specification. This affects all dependent claims.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 11, 13, and 16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a fusion protein that inhibits the function in the class of gonadotropins and BHV, does not reasonably provide enablement for a fusion protein that inhibits the function of any endogenously made protein and protects against any disease in a vertabrate. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. This affects all dependent claims.

The claims are drawn to eliciting a dual immune response against a fusion protein. An immune response against a portion of the fusion protein inhibits the activity of an endogenous protein and another portion is used to elicit an immune response against an antigen. The specification on page 10, lines 20-23 states that the endogenous protein function that is to be inhibited is not limited to hormones or enzymes, and is intended to mean any natural protein made by the animal. The specification has not described the structure or function for all of the possible proteins made in a vertebrate, or what result of inhibiting the function of any protein would do to the vertebrate when administered, except for GnRH. Nor does the specification illustrate that incorporating any protein from any pathogen into the claimed fusion protein protects against every disease. While the specification describes various proteins on page 11, line 14- page 12, line 15 whose function can possibly be inhibited by an immune reaction, the examples on page 34-43 are limited to the fusion protein gD/GnRH. The specification does not

enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. An undue amount of experimentation would be required of the skilled artisan to inhibit every protein made in an invertebrate while protecting against every disease that may be encountered by the vertebrate by administering the claimed fusion protein. The specification has not provided adequate guidance for the skilled artisan to make and use the entire genus of materials claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Der Zee et al. (5,684,145) and Mittal et al. for reasons of record.

Applicant argues improper hindsight reasoning and further states that there was nothing in either reference that suggests a combination of the two references. The applicant argues that Mittal. et al. does not teach that gD can be used as a carrier protein.

Applicant's arguments have been considered, but are unpersuasive. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention

was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the test of obviousness is not an express suggestion of the claimed invention in any or all references but what references taken together would suggest to those of ordinary skill in the art presumed to be familiar with them.

Van Der Zee et al. teaches that GnRH itself is non-immunogenic and therefore needs a strong immunogenic carrier to elicit an effective immune response against GnRH that have strong antigenic properties (emphasis added), see columns 2-5. Mittal et al. teaches that a full-length recombinant form (gD) from BHV-1 inserted into a human adenovirus type 5 vector had the same antigenicity of both proteins is equivalent to native gD expressed in BHV-1 infected cells, see the abstract. Furthermore, since it was previously known in the art that gD is highly antigenic on its own, it would be obvious to one of ordinary skill in the art to use such an antigenic protein as a carrier, or a part of a fusion protein. Moreover, it is conventional practice in the vaccine arts to incorporate highly antigenic glycoproteins into a vaccine; therefore, one of ordinary skill in the art would view the incorporation of gD into the hybrid protein taught by Van Der Zee as an obvious substitution over the *E. coli* fimbrial-filiments, if one were interested in

treating cows with BHV. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon A. Foley whose telephone number is (703) 308-3983. The examiner can normally be reached on 7:30-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4426 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Shanon Foley/SAF
October 1, 2001

James C. Housel 10/1/01

JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600